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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/550,471 | 04/14/2000 | TODD ALLEN BERG | VS-42 | 8796 |

1473 7590 10/30/2002
FISH & NEAVE
1251 AVENUE OF THE AMERICAS
50TH FLOOR
NEW YORK, NY 10020-1105

EXAMINER

SNOW, BRUCE EDWARD

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3738

DATE MAILED: 10/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary

Application No.

09/550,471

Applicant(s)

BERG ET AL.

Examiner

Bruce E Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8, 9, 11-24, 26, 28, 29, 31-50, 52 and 53 is/are pending in the application.
- 4a) Of the above claim(s) 2, 6, 8, 11-19, 21, 22, 26, 28, 31-44, 50 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 9, 20, 23, 24, 29, 45-49 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/1/02 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 3-5, 9, 20, 23-24, ~~27~~, 29, 45-49, 53 are rejected under 35

U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bessler et al (5,855,601).

Referring to all figure, specifically figure 7, Bessler et al teaches a heart valve apparatus comprising a uni-directional valve portion 22, 63; a connector band 32, 50, or 62; a plurality of fingers 64 which "*are oriented substantially parallel to the direction of blood flow*". Bessler et al specifically names elements 64 as "barbs" and inherently most fulfill the language as being "barbed fingers".

In the alternative:

Bessler et al teaches elements 64 are directed in the claimed orientation as being "*oriented substantially parallel to the direction of blood flow*," however, it is unclear as to the elements being "barbed fingers". Despite the figures failing to show an arrow or fishhook configuration, given the fact that the specification teaches "barb", it would have been obvious to one having ordinary skill in the art to use such a configuration ("well-know sense" applicant's arguments page) for better anchoring.

Regarding barbs, see column 4, line 12.

Regarding the gasket, see element 25.


Claims 20, 23-24, 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Frantzen et al (5,843,164).

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Frantzen al teaches a connector band having a plurality of fingers 20, 34 which *"are oriented substantially parallel to the direction of blood flow"*. Regarding the gasket around the outer circumference of the band, see graft 52. The gasket 52 is fully capable for sealing between said band and a tissue annulus.

Claims 20, 23-24, 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Lazarus (6,416,535)

Referring to all figures and embodiments, specifically figure 11, Lazarus teaches a connector band having a plurality of barbed fingers 139 which *"are oriented substantially parallel to the direction of blood flow"*. Regarding the gasket around the outer circumference of the band, see graft 12. The gasket 12 is fully capable for sealing between said band and a tissue annulus.

 Claims 1, 3-5, 9, 20, 23-24, ~~27~~, 29, 45-49, 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Griffin et al (6,241,765).

Referring to all figure, Griffin et al teaches a heart valve apparatus comprising a uni-directional valve portion including 16, 18; a connector band including 57; a plurality of fingers 90 which *"are oriented substantially parallel to the direction of blood flow"*. See figure 7 teaching fingers 90 can be barbed. Regarding the gasket, see element 80.

Response to Arguments

Applicant's arguments dated 10/1/02 have been fully considered.

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Regarding the Bessler et al rejection, the Examiner's position is believed to clearly stated in the grounds of rejections.

Regarding the Frantzen et al rejection, the Examiner's position is believed to clearly stated in the grounds of rejections. Additionally, "a tissue annulus" does not infer a heart valve tissue annulus, however, the device of Frantzen et al could operate in that location also, fulfilling all functional language.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

bes
October 23, 2002

A handwritten signature in black ink, appearing to be 'BS' followed by a long, sweeping horizontal line.

**BRUCE SNOW
PRIMARY EXAMINER**